

## REMARKS

### *The Present Invention*

The present invention relates to a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase and composition for the aforementioned method.

### *The Pending Claims*

Claims 1-31 are currently pending. Claims 1-17 and 31 are directed to a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. Claims 18-30 are directed to a composition comprising a vacuolar-type (H<sup>+</sup>)-ATPase inhibiting compound.

### *Amendments to the Claims*

Claims 1, 2, 5, 6, 8, and 31, have been amended. No new matter has been added by way of these amendments.

### *Summary of the Office Action*

Claims 1-17 and 31 are objected to as containing non-elected subject matter. Claims 1, 3-8, 15, and 16, stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable any person skilled in the art to which it pertains to prevent a condition treatable by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. Claims 1-17 and 30, stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable any person skilled in the art to which it pertains to treat any condition by the inhibition of vacuolar-type(H<sup>+</sup>)-ATPase by the method of the invention. Claims 1-4, 12-18, and 31, stand rejected under 35 U.S.C. § 102 as being anticipated by Boyd et al. (WO 99/05136). Claim 6 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boyd. Claims 8-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boyd in view of Holt et al. (WO 93/18652) and Yamamoto et al. (Cell Struct. Funct. 1998, 23, 33-42).

### *Examiner Interview*

The applicant wishes to thank Examiners Mitchell and Padmanabhan for the courtesies extended to the applicant's representative during the telephone interview that took place February 22, 2005. In light of the interview, the applicant understands that the restriction

requirement will be withdrawn if the claims 1, 2, and 5, are amended to limit the Z-linker to a contiguous "chain of 7-10 atoms". Accordingly, claims 1, 2, and 5 have been so amended.

*Discussion of Restriction Requirement*

Pursuant to the amendments to claims 1, 2, and 5, to limit the Z-linker to a contiguous "chain of 7-10 atoms" made in view of the Examiner Interview, the applicant understands that the restriction requirement will be withdrawn. The applicant would also like to note that claims 6, 7, and 18-31, comprise, *inter alia*, a Z-linker having a contiguous chain of 0-6 atoms.

*Claim Objection*

Pursuant to the amendments to claims 1, 2, and 5, made in view of the Examiner Interview, the objection to the claims is moot.

*Rejections under 35 U.S.C. § 112, First Paragraph*

Claims 1, 3-8, 15, and 16, stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable any person skilled in the art to which it pertains to prevent a condition treatable by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. The applicant requests that the rejection to claims 1, 3-5, 8, 15, and 16, be withdrawn in view of the amendment to independent claim 1. The applicant further requests that the rejection to claims 6 and 7 be withdrawn in view of the amendment to independent claim 6.

*Rejections under 35 U.S.C. § 112, First Paragraph*

Claims 1-17 and 30, stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable any person skilled in the art to which it pertains to treat any condition by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase by the method of the invention. The Applicant requests that the rejection to claims 1-5 and 8-17 be withdrawn in view of the amendment to independent claim 1. The Applicant further requests that the rejection to claims 6 and 7 be withdrawn in view of the amendment to independent claim 6. Finally, the Applicant requests that the rejection to claim 30 be withdrawn in view of the fact that claim 30 is directed to a composition and not a method of treating.

*Rejections under 35 U.S.C. § 102*

Claims 1-4, 12-18, and 31, stand rejected under 35 U.S.C. § 102 as being anticipated by Boyd et al. (WO 99/05136) (“Boyd”). Although Boyd discloses the compounds salicylihalamide A and salicylihalamide B, it does not disclose a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase.

The Office Action states that “the administration of a compound of formula (I) to a patient for the treatment of cancer will inherently treat a patient for a disease treatable by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase” (Office Action, p. 14). Boyd does not anticipate the pending claims by inherent disclosure. “[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation...” *Transclean Corp. v. Bridgewood Services, Inc.*, 62 USPQ2d 1865, 1871 (Fed. Cir. 2002). The allegedly anticipatory inherent feature must be inevitable, not merely possible or probable. As stated in the specification, “a given vacuolar-type (H<sup>+</sup>)-inhibitory compound may preferentially inhibit vacuolar-type (H<sup>+</sup>)-ATPase activity in one or more kind or location of intracellular organelle, plasma membrane, cell or tissue. Thus, the skilled practitioner will typically select a particular vacuolar-type (H<sup>+</sup>)-ATPase inhibitory compound for a desired therapeutic use.” (Specification p. 40, line 27 - p.41, line 3) Hence, the inherent feature is not inevitable. In addition, nowhere does Boyd explicitly disclose a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. Therefore, Boyd cannot inherently anticipate the pending claims.

The Applicant requests that the rejection to claims 1-4, 12-18, and 31, be withdrawn.

*Rejections under 35 U.S.C. § 103*

Claim 6 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boyd. The Office Action states that Boyd teaches a method of treating cancer. Claim 6 is directed to a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. As mentioned above, Boyd does not disclose the method of claim 6. The Applicant requests that the rejection to claim 6 be withdrawn.

Claims 8-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boyd in view of Holt et al. (WO 93/18652) (“Holt”) and Yamamoto et al. (Cell Struct. Funct. 1998, 23, 33-42) (“Yamamoto”). The Office Action states that Boyd teaches a method of treating cancer. However, Boyd does not teach a method of treating an intra-organellar acidification of intracellular organelles by the inhibition of vacuolar-type (H<sup>+</sup>)-ATPase. The combination

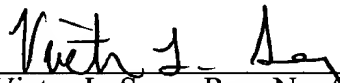
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of Holt and/or Yamamoto with Boyd does not cure the deficiencies of Boyd. The Applicant requests that the rejection to claims 8-11 be withdrawn.

*Conclusion*

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

  
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